PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant: Stinson, J.	Examiner: Sweet, Thomas
Application No.: 10/721,702	Group Art Unit: 3738
Filed: November 25, 2003	Docket: 792-64 DIV II
For: BIOABSORBABLE ENDOPROSTHESIS HAVING ELONGATE AXIAL RESERVOIR FOR BY-PRODUCT COLLECTION	Dated: August 12, 2008

Confirmation No.: 6272

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REPLY BRIEF PURSUANT TO 37 C.F.R. §41.41

Sir:

Pursuant to 37 C.F.R. §41.41, Appellant files this Reply Brief in response to the Examiner's Answer of June 23, 2008. Appellant's Reply Brief is timely filed on or before August 23, 2008.

Appellant addresses particular points and continue to rely on the arguments of the main Appeal Brief. Section A of this Reply Brief revises the Summary of the Claimed Subject Matter. Section B of this Reply Brief briefly describes the hollow reservoir portions of the present invention. Section C of this Reply Brief further describes the deficiencies of the main applied reference.

A. Under Section V. of the Appeal Brief, Please consider the following Summary of Claimed Subject Matter:

The present invention as set forth independent claim 30 is directed to a bioabsorbable endoprosthesis 50. The endoprosthesis 50 consists essentially of a plurality of elongate elements 20, 30 having an outer surface. (Specification, page 12, lines 2-3; FIG. 5). The elements 20, 30 include a bioabsorbable polymer adapted to undergo degradation *in vivo*. (Specification, page 9, lines 15-16). The elements 20, 30 also include an elongate, axially extending reservoir portion 22, 32 adapted to collect a by-product of the degradation of the bioabsorbable polymer. (Specification, page 9, lines 4-5; FIGS. 2A and 2B). Desirably, the elements 20, 30 occupies a total element volume including a reservoir volume occupied by the at least one reservoir portion 22, 32 where the reservoir volume should be at least about ten percent of the total element volume. (Specification, page 10, lines 2-5).

Claim 81 depends from claim 30. This dependent claim sets forth the number of filaments 20, 30 and their thickness that may be used for the endoprosthesis 50 of claim 30. Desirably, the number of elements, N, is equal to about $(D/(0.022D + 0.17)) \pm 4$ filaments, where D, in mm, is the free state diameter of the endoprosthesis 50. (Specification, page 9, lines 22-23). Desirably, the elongate elements 20, 30 have a thickness, t in mm, of about $(D/(1.8D + 15)) \pm 0.03$ mm, where D, in mm, is the free state diameter of the endoprosthesis 50. (Specification, page 9, lines 20-22).

The present invention as set forth independent claim 82 is directed to a braided bioabsorbable endoprosthesis 50. (Specification, page 8, lines 1-5; FIG. 5). The bioabsorbable endoprosthesis 50 comprises a plurality of elongate elements 20, 30 interbraided into a tubular, radially expandable structure. (*Id.*). The elongate elements 20, 30 have an outer surface and include a bioabsorbable polymer adapted to undergo degradation *in vivo*. (Specification, page

9, lines 15-16). The elements 20, 30 include an elongate, axially extending reservoir portion 22, 32 adapted to collect a by-product of the degradation of the bioabsorbable polymer. (Specification, page 9, lines 4-5; FIGS. 2A and 2B). Each of the elements 20, 30 occupies a total element volume including a reservoir volume occupied by the at least one reservoir portion, and the reservoir volume is at least about ten percent of the total element volume. (Specification, page 10, lines 2-5). The number of elements, N, is equal to about (D/(0.022D + 0.17)) ± 4 filaments, where D, in mm, is the free state diameter of the tubular structure. (Specification, page 9, lines 22-23). The elongate elements 20, 30 have a thickness, t in mm, of about (D/(1.8D + 15)) ± 0.03 mm, where D, in mm, is the free state diameter of the tubular structure 50. (Specification, page 9, lines 20-22).

B. Hollow Reservoirs of the Present Invention:

The present invention is directed to an endoprosthesis formed from a plurality of hollow bioabsorbable filaments. (Specification, page 14, second full paragraph, lines 1-7). Bioabsorbable filaments, including hollow bioabsorbable filaments, are not as strong as metallic filaments. (Specification, page 8, first fill paragraph, lines 1-5). Nevertheless, the bioabsorbable endoprosthesis of the present invention is configured to have the same or similar radial strength to a stent made from stronger metallic filaments. (Specification, page 8, first fill paragraph, lines 5-8). The strength of the endoprosthesis of the present invention is achieved without the use of other stent structures, such a tubular main body supporting the filaments as present in the prior art. (Specification, page 18, second fill paragraph, lines 1-4).

Degradation of a bioabsorbable material, such as PLLA or PGA, occurs when the material absorbs water and undergoes hydrolytic scission. (Specification, page 13, first fill paragraph under the Detailed Description; second paragraph under the Detailed Description,

lines 3-4). The rate of degradation is generally higher at a location having lower pH as acidic environments catalyze degradation. (Specification, page 15, first full paragraph, lines 3-5). With the hollow reservoirs of the present invention acidic by-products from degradation are stored in the reservoirs and these acidic by-products advantageously accelerate degradation in the inner surfaces of the bioabsorbable members. (Specification, page 15, first full paragraph, lines 5-7). Thus, the bioabsorbable elongate elements of the present invention will hollow reservoirs will degrade faster than solid members having no internal elongate reservoirs. Therefore, the hollow reservoirs are a critical claimed feature of the present invention.

The claimed hollow reservoirs of the present invention are in direct contrast to the main body 11 of Buscemi. In other words, the main body 11 of Buscemi does not have internal reservoirs where acidic by-products from degradation may be stored. The apertures 14 of Buscemi are holes through the main body 11 and are not reservoirs internal to the main body where acidic by-products from degradation may be stored.

C. Main Tubular Body of Buscemi:

i) Buscemi inoperable if modified to remove its main body 11.

Buscemi clearly shows the main body 11 of the stent 10 is an essential feature of its device. For example as depicted in Figure 1, the fibers 18 (i) are clearly disposed over only portions of the main body 11 and are not disposed over apertures 14, 26 of the main body 11; (ii) are clearly not interconnected with one another; and (iii) each have opposed ends separated by a gap over the apertures 14, 26. With such a structure, the fibers 18 do not form a tubular endoprosthesis by themselves without the necessary main body 11, especially when fibers are to be absent from the open apertures 14, 26. Exclusion of the fibers 18 from the open apertures 14, 26 of the main body 11 would make the fibers 18 inoperable as a endoprosthesis when the

main body 11 is removed because the fibers would not form a self-supporting tubular endoprosthesis, regardless whether the fibers 18 of Buscemi are annularly wound, braided or woven.

An inoperable reference, such as the stent 10 of Buscemi without its main body 11, cannot form a basis for a *prima facie* case of obviousness. *In re Gordon et al.*, 221 U.S.P.Q. 1125, 1127 (CAFC 1984). Indeed, such an inoperable device is a teaching away from the present invention. *Id.*

ii) Specification clearly notes what is included:

The specification clearly indicates that elongate elements having hollow reservoirs, are to be used to form the stent to the exclusion of other stent structures, as follows:

> **The tubular and self-expandable body or structure form by the interwoven filaments 20, 30, 40 is a primary prosthetically-functional structure of stent 10, and for this reason the device can be considered to substantially consist of this structure to the exclusion of other structures.**
> (Specification page 18, paragraph beginning with "The tubular and …", lines 1-4) (emphasis added)

Thus, the Specification teaches that main tubular wall, such as the main body 11 of Buscemi which does not have any internal elongate reservoir portions, is to be excluded from the scope of the claims.

iii) Inclusion of the main body 11 of Buscemi would materially change the characteristics of the claimed invention:

The specification clearly describes the basic and novel features of the inventive stent having accelerated degradation achieved by filaments having a reservoir, as follows:

> **FIGS. 3a-3f illustrate cross-sections of a known member 10….The degradation rate nearer to the surface 14 of member 10 is relatively slower because pH level at the**

> **surface 14 is not substantially changes since acid degradation by-products are more readily flushed or diffused away.** (Specification page 13, paragraph beginning with "In comparison…", lines 1-3) (emphasis added)
>
> **[F]ilaments [of the present invention] … advantageously provide accelerated degradation features compared to known materials. The filaments or elongate members have reservoir portions….** (Specification page 14, paragraph beginning with "FIGS. 3a-3f illustrate …", lines 1-12) (emphasis added)

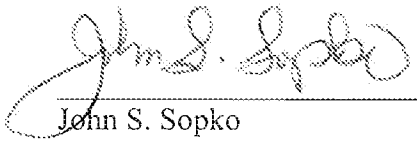
Buscemi fails to disclose, teach or suggest that its main tubular body contain elongate, hollow reservoir portions within its main body 11. Inclusion of the main body 11 of Buscemi would materially change the characteristics of the claimed invention because it would necessarily impart a major stent structure which does not have a hollow reservoir. The device of the present invention consists essentially of elongate bioabsorbable filaments having internal reservoirs so that degradation of each bioabsorbable elements is advantageously accelerated. Inclusion of the main body of e Buscemi would not only materially change the characteristics of the claimed invention, but would defeat the very purpose and intent of the present invention.

Summary

Thus, for the reasons set forth herein and set for in the Appeal Brief, claims 30, 44, 46, 50-59 and 76-84 are patentably distinct over the applied references. Withdrawal of the rejection of claims 30, 44, 46, 50-59 and 76-84 is respectfully requested. Allowance of claims 30, 44, 46, 50-59 and 76-84 are further respectfully requested.

Furthermore, entry and allowance of the withdrawn claims 45 and 47-49 are respectfully requested.

Respectfully submitted,



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